

# Grant Administration

*This chapter is adapted from the Dartmouth College Office of Sponsored Research Sponsored Research Manual. Please note that some of the information presented is specific to Dartmouth College policies and may vary from institution to institution. The proposal submission and review process may also vary from institution to institution. For more information or to access the complete manual, please visit the Dartmouth College Office of Sponsored Research website at [www.dartmouth.edu/~osp](http://www.dartmouth.edu/~osp).*

## Introduction

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“Sponsored projects are research, training, or instructional projects involving funds, materials, other forms of compensation, or exchanges of in-kind efforts from sources external to [Dartmouth] College under awards or agreements which contain any one of the following criteria:”

1. “The award or agreement binds the college to a scope of work that is specified in an investigator’s particular research project. “
2. “The sponsor defines a period of performance during which funds may be used or unused funds must be returned to the sponsor.”
3. “A line item budget is involved. A line item budget details expenses by activity, function, or project period. The designation of indirect or administrative costs qualifies a budget as ‘line item.’”
4. “Financial reports are most frequently required and the expenses are subject to audit.”
5. “The award or agreement provides for the disposition of tangible or intangible properties that may result from the project. Tangible properties include equipment, records, formal activity reports, theses, or dissertations. Intangible properties include rights in data, copyrights, inventions or research related materials” (1).

## Office of Management and Budget: Circulars A-21 and A-110

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The administration of federally sponsored research projects within educational institutions is monitored and guided by Office of Management and Budget (OMB) Circulars A-21 and A-110. While each institution is encouraged to conduct research and education activities in a manner consonant with its own academic philosophies and institutional objectives, OMB Circular A-21 outlines federal regulations governing the cost accounting principles of those federally funded research projects, and OMB Circular A-110 sets forth standards for obtaining consistency and uniformity among federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and other non-profit organizations. Although researchers are not expected to know specific applications of OMB circulars, they should understand that many of the policies and procedures orchestrated by the Dartmouth College Office of Sponsored Projects (OSP) reflect local application of federal regulations. The salient points of OMB Circulars A-21 and A-110 of which all staff engaged in sponsored research should be aware are the following:

- Each institution involved in sponsored research is expected to employ sound management practices.
  - Arrangements for sponsored research funded by federal agencies are negotiated between the agency and the institution.
  - There are prescribed policies and procedures that govern the management of sponsored research funds.
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## **Pre-Award Project Development**

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Acknowledging that proposal development is extremely time consuming, this section addresses the skills and pertinent information potential researchers need in the early stages of proposal development. The researcher will become acquainted with the rudiments of how to develop a general proposal and those policies Dartmouth College requires be followed before a proposal is submitted to a potential funding agency, foundation, or corporation.

The process of taking a thought, data, or creative concept and moving it from the idea stage to a fundable sponsored research project can be long and frustrating. The process is even more discouraging if the final proposal is not funded. Initiating a sponsored research project not only commits the researcher's efforts, but also the resources of an institution. Dartmouth College has developed guidelines and procedures aimed at both encouraging sponsored research and protecting the institution's reputation and financial assets. Researchers need to know and follow these procedures. A proposal is institutional whenever the application is to a federal agency, foundation, or corporation that does not give to individuals or when the researcher is asking the institution to help support a project through cost-sharing or indirect costs. Researchers must also realize that each potential sponsor has its own set of guidelines and requirements that must be followed.

## **Proposal Development**

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In the earliest stage of a proposal, a researcher must develop an idea into a clearly articulated goal that can answer the question, "what does the researcher hope to accomplish with the completion of this project?" This overarching goal forms the backdrop for presenting a proposal that can successfully describe a solid and realistic work plan and budget and provide some assurance to the sponsor that the award will be used to its best advantage. The proposal must quickly and easily provide answers to these questions:

- What will the research accomplish, how much will it cost, and how much time will it take?
- What is the plan for completing the research?
- How will the results be evaluated?
- How does the proposed project relate to the sponsor's interests?
- Why should you, rather than someone else, do this project?
- What has already been done in the area of the project?
- What difference will the project make to the institution, students, the discipline, or whatever appropriate categories are identified?

There are two schools of thought on proposal writing. The first recommends that a researcher develop a full proposal then seek to identify potential funding sources. The second approach counsels that one develop the research idea, identify the most promising potential sponsors, then develop the full proposal in a style and presentation that would be most appealing to the identified sponsor. Both approaches have their merits and weaknesses. The latter approach, however, is most frequently recommended and is assumed in this manual.

Requests for applications (RFAs) and requests for proposals (RFPs) are special types of proposals.

RFAs are formal announcements that describe an initiative in a well-defined area and invite researchers in the field to submit a grant application. Attributes of RFAs include:

- Frequently are one-time competitions.
- Limited number of awards may be made.
- Specific dollar amount is allocated to each award.

RFPs are a sponsor's request for bids on a project. Attributes of RFPs include:

- Sponsor solicits pricing or technical proposals to supply goods or services as specified in the requesting document.
- The proposal procedure is often complex and must satisfy very specific requirements.
- Any resulting award(s) would normally be funded by a contract.

## **Funding Sources**

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Having developed a well-articulated research question, the next step is to identify appropriate funding sources. Sponsored projects fall within several general functional categories. Examples of those categories are research, training, curriculum development, public services, fellowships, art exhibitions, and equipment awards. Sponsors of those activities include the federal government, state and local governments, foundations, international organizations, research institutes, and corporations. The successful funding of a project will be determined by how well the researcher matches the project's scope with a sponsor's mission and interests.

There are several starting points possible for initially identifying potential funding sources. This manual includes a listing of available sources for identifying potential sponsors (appendix online). A few examples are provided below.

### **Dartmouth Office of Sponsored Projects**—[www.dartmouth.edu/~osp/](http://www.dartmouth.edu/~osp/)

The Office of Sponsored Projects (OSP) has recently developed a website to facilitate sponsored research efforts of the Dartmouth community. The website provides a quick and direct link to the most useful funding sources.

### **Community of Science**—[www.cos.com](http://www.cos.com)

The Community of Science website provides a quick reference point for expertise, inventions and facilities, federally-funded research in the United States, the *Commerce Business Daily*, and the *Federal Register*.

### **Academic Research Information System (ARIS)**—[www.arisnet.com](http://www.arisnet.com)

This site provides up-to-date information on federal and private sources of grants, fellowships, scholarships, contracts, and awards. ARIS publishes three reports covering the areas of creative arts and humanities, social and natural sciences, and biomedical sciences. The reports are issued every six weeks to provide current information on funding opportunities and upcoming deadlines.

**Foundation Center**—[www.fdncenter.org](http://www.fdncenter.org)

The Foundation Center is an independent nonprofit information clearinghouse established in 1956. The center's mission is to foster public understanding of the foundation field by collecting, organizing, analyzing, and disseminating information on foundations, corporate giving, and related subjects. The audiences that call on the center's resources include grant seekers, grant makers, researchers, policy makers, the media, and the general public.

**ScienceWise**—[lite.researchresearch.com](http://lite.researchresearch.com)

This site contains information about federal grant opportunities for educational and research communities in the United States as well as opportunities in other countries.

***Chronicle of Higher Education***—[chronicle.com](http://chronicle.com)

This site offers a guide to each week's *Chronicle*, events, deadlines, congressional hearings important to higher education, a list of best-selling books, information from selected advertisers, and complete job listings.

In targeting potential sponsors, the researcher must match the characteristics of a proposal with the guidelines and interests of each sponsor. Carefully read each sponsor's requirements, funding interests, and submission guidelines and look at past projects funded by specific sponsors. Reviewing successfully funded proposals provides a realistic portrait of a sponsor's interests. Taking the time to identify the best potential funding sources for a particular research project will increase the likelihood of funding success. Key matching points include:

- Goals of the research project match the mission and interests of the queried sponsor.
- Amount of funding requested falls within the normal funding range of the queried sponsor.
- An established relationship with the potential funding source. This relationship can be the result of past successfully executed awards, professional contacts, or professional reputations of the institution and researcher.

## **Initial Contact with a Sponsor**

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The approach a researcher takes in contacting potential sponsors will be contingent on the administrative area to which one reports and the type of sponsor from which the researcher is seeking funding. There are cases where a researcher should not contact a potential sponsor without prior approval. Clearance is required for all institutional approaches to foundations and corporations and should be obtained before a contact is made or a proposal is written. Prior approval or clearance is not needed when contacting a government agency for potential funding.

A researcher does not need clearance to apply to government funding agencies. The OSP maintains listings of current program officers and other representatives of federal funding agencies, plus information about specific initial contact requirements or guidelines. Program officers are usually a good initial point of contact for faculty wishing to discuss the scope of their project and guidelines unique to the agency.

A key element of successful proposal writing is establishing a relationship with a potential funding source early on in the process. A contact at the funding agency can facilitate writing the full proposal, serve as a resource for answering questions, and shepherd the proposal through the review process.

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Specifically, the purpose of the initial contact is to confirm the common areas of interest of the sponsor and the researcher. These inquiries can take the form of phone conversations or written correspondence in the form of a letter of inquiry. A letter of inquiry is initiated by an applicant to determine if a proposed project is within an agency’s fundable program area and to request agency policy and program information, as well as instructions and forms. One should always address a letter of inquiry to a specific person to begin the relationship development process. Inquiries, either by phone or letter, should address the following basic questions:

- What do you intend to do?
- Why do you want to do it?
- How will you do it?
- What do you estimate the project will cost?
- When and where will you do it?
- Who are you and what are your qualifications?
- Who will benefit from this work?

## **Proposal Development Timetable**

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The **Table** is intended to serve as a guide for those working on proposals. Scheduling of proposal tasks will be somewhat unique for each proposal developed. However, this timetable can serve as a general guide in anticipating the time needed to create a proposal.

**Table**  
**Proposal Development Timeline**

30-90 days before a proposal is due in the hands of a sponsor	<ul style="list-style-type: none"> <li>• Review program announcement, guidelines, and instructions.</li> <li>• Obtain clearance from the Development Office or appropriate administrator to approach sponsor (for non-government sponsors).</li> <li>• Prepare outline or first draft of research/program plan.</li> <li>• Contact human or animal subjects administrator, as needed.</li> <li>• Coordinate with participating organizations/institutions.</li> <li>• Discuss effort, cost sharing, and matching funds with chair, academic dean, or area administrators.</li> </ul>
25-30 days before a proposal is due in the hands of a sponsor	<ul style="list-style-type: none"> <li>• Meet with OSP staff for consultation and coordination of proposal, as needed.</li> <li>• Discuss cost estimating process for the proposed project.</li> </ul>
20-25 days before a proposal is due in the hands of a sponsor	<ul style="list-style-type: none"> <li>• Preparation of preliminary budget.</li> <li>• Share draft of proposal with colleagues/research committee.</li> </ul>
15-20 days before a proposal is due in the hands of a sponsor	<ul style="list-style-type: none"> <li>• Submit draft of budget and justification, narrative, and sponsor forms to OSP grants specialist for review to ensure compliance with college and sponsor requirements.</li> </ul>
5-15 days before a proposal is due in the hands of a sponsor	<ul style="list-style-type: none"> <li>• Respond to questions by OSP staff, make changes as needed.</li> <li>• Proofread and prepare final copy of proposal.</li> <li>• Route complete proposal to department chair, area administrator or dean for approval.</li> </ul>
2-5 days before a proposal is due in the hands of a sponsor	<ul style="list-style-type: none"> <li>• Principal investigator forwards proposal, routing form, and any needed attachments to OSP for final review.</li> <li>• Principal investigator arranges for photocopying and mailing of proposal to sponsor.</li> </ul>

## Application Guidelines

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While it may appear self-evident, application guidelines and submission deadlines for sponsored funding should be followed exactly. A significant percentage of proposals are not funded each year because the application guidelines were not followed. Sponsors frequently spell out the requirements for their applications in very specific terms. These organizations can and do return proposals without a review if the proposals do not conform to the directions provided by the potential sponsor.

Page limits, typeface size, and other restrictions are taken seriously by sponsoring organizations. Often, sponsors request a preliminary or shorter proposal (three to five pages) before asking for a complete final proposal. Take the same care and effort with pre-proposals as with the final proposal. In particular, faculty should pay careful attention to all of the following in preparing the proposal:

- Page length of the proposal.
- Specifications on the typeface size.
- Limitations placed on the length of resumes or other appendix materials.
- The deadline date for submission of the proposal:
  - Date of delivery at the agency.
  - Date by which proposal must be stamped with official US Postal Service postmark.
- Note what pages must be submitted as originals versus pages that are acceptable for submission as copies.
- Specific number of copies of proposal to be submitted.
- Certifications or assurances to be sent with proposal.

## What Constitutes a Proposal

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A proposal, simply put, is a plan. It is developed with the idea that a potential funding agency, foundation, or corporation will find merit in the plan and be willing to commit support to its execution. A proposal also binds the institution to a plan whenever the application is to a foundation or corporation that does not give to individuals, or when the researcher is asking the institution to help support a project through cost-sharing indirect costs or other forms of contribution made by the college. Seen in this light, a good proposal will bring together the skills of argument, persuasion, and the ability to clearly articulate a project's goals, but will also take into consideration the resources and mission of the home institution.

### Types of Proposals

**New Proposal:** A new proposal is one that is submitted for initial funding. Most new proposals are submitted for competitive review by the funding organization and peer review. The criteria for review and evaluation are predetermined by the funding organization and are usually included as part of the initial proposal information provided by the funding organization.

**Continuation Proposal or Non-Competing Continuation:** Frequently, government-sponsored awards are distributed on a year-by-year or incremental basis. Though the award may have been approved for multiple years, the principal investigator must submit a continuation proposal to receive annual funding allotments.

**Renewal Proposal or Competing Continuation:** A renewal proposal requests funds to continue the project beyond the initially approved length of the project. Renewal proposals are usually evaluated with the same criteria as a new proposal. The principal investigator must be aware of submission deadlines and should generally treat a renewal proposal as a new proposal.

**Contract Proposal:** A contract proposal is often in direct response to a RFA or RFP. The institution agrees to undertake specific and narrowly defined tasks as defined and controlled by the funder.

**Revised Proposal:** A revised proposal is one that has been informally acknowledged as fundable by a sponsor with the stipulation that specific changes must be made. The revised proposal is then resubmitted for funding consideration.

**Supplemental Proposal:** A supplemental proposal asks for additional funding to expand a program or project's scope or research protocol. As outlined in a specific sponsor's guidelines, a supplemental proposal may be treated as a new proposal for the purposes of review and competition for funds.

## **Generic Format of a Formal Proposal**

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*The following section describes in detail how to develop a generic proposal. It is intended for individuals who have minimal background in proposal development or looking for reference information about proposal writing. Please be aware that some sponsors, such as the National Institutes of Health, have very specific guidelines for developing and submitting a proposal. In all cases, individual sponsor guidelines should be followed.*

There are three major components to the standard research proposal: the text, the budget, and the supporting documents, referred to as the appendices, attachments, or exhibits. This section outlines each piece of the proposal and concludes with a discussion of certain variations in format required if seeking support for other kinds of academic programs.

**Cover Sheet or Face Page:** Most sponsoring agencies specify the format for the cover sheet and some provide special forms to summarize basic administrative and fiscal data for the project. Generally, the principal investigator, his or her department head, and an official representing the institution sign the cover sheet. In addition, the cover sheet usually includes the institution's reference number for the proposal, the name of the agency to which the proposal is being submitted, the title of the proposal, the proposed project period, the total funds requested, the name and address of the institutional unit submitting the proposal, and the date submitted. Some agencies want the cover sheet to specify whether the proposal is for a new or continuing project. The cover page must be signed by an authorized administrative official from OSP. Follow the directions for completing a cover sheet exactly.

While most sponsors require applicants to fill out an official cover page for the proposal, in the absence of that cover page, applicants should include a cover letter on Dartmouth College stationery addressed to the sponsoring organization specifying the following information:

- Project title.
- Project summary.
- Total cost of project.

- Funds requested from sponsor.
- Name, position, address, phone number, email, and fax number of principal investigator.
- Signature block for principal investigator.
- Signature block for sponsored projects administrative official.
- Address, phone number, email, and fax number of OSP.

**Title Page:** Although titles should be comprehensive enough to indicate the nature of the proposed work, they should also be brief. One good way to cut the length of titles is to avoid words that add nothing to a reader's understanding, such as "Studies on...," "Investigations...," or "Research on Some Problems in..." A good title is usually a compromise between conciseness and explicitness.

The title page should include not only the title of the project, but also the submission date, to whom the proposal is being submitted, and the name of the institution submitting the proposal.

**Abstract or Project Summary:** Every proposal, even a very brief one, should have an abstract. Some reviewers read only the abstract, and most readers rely on it to give them an initial quick overview of the proposal and later to refresh their memory of the project's main points. Agencies often use the abstract alone in their compilations of research projects funded or in disseminating information about successful projects

The abstract speaks for the proposal when it is separated from it, provides the reader with a first impression of the request, and, by acting as a summary, frequently provides the reader also with his or her last. It is the single most important element in the proposal.

To present the essential meaning of the proposal, the abstract should summarize or address all the questions identified in the "Proposal Development" section of this manual, with the exception of the cost of the project. The project cost is excluded from the abstract because the abstract is often subject to a wider public distribution than the rest of the proposal.

Although it often appears at the beginning of the proposal, the abstract should be written last. A concise summary (approximately 200 words) of the proposal, the abstract should appear on a page by itself (numbered with a small Roman numeral if the proposal has a table of contents and with an Arabic number if it does not).

**Table of Contents:** The convenience of the reader should be the guiding consideration in producing a table of contents. Very brief proposals with few sections ordinarily do not need a table of contents. Long and detailed proposals should list all major parts and divisions, including the abstract and significant preliminary pages. Subdivisions usually need not be listed. The table of contents may require a list of illustrations (or figures) and a list of tables. If all of these items are included, they should follow the order presented in the text, and each should be numbered with lower-case Roman numerals. The table of contents should be simply labeled "Contents" in the header of the page.

**Introduction:** The introduction to a proposal sets the tone. The researcher must appear appropriately confident, organized, and clear as to the intent of the research to be undertaken. The introduction should begin with a capsule statement of what is being proposed and then should proceed to introduce the subject

to someone unfamiliar with the topic. Proposal writers cannot assume that the reviewer is familiar with the topic. The introduction should briefly outline the goals and objectives of the project, how long it will take, and give enough background to enable the reviewer to place this particular research problem in a context of common knowledge.

The introduction should very specifically and concisely state the importance of the research being proposed. The introduction may introduce the concept of how this project's approach and resulting work will advance the field of knowledge and prove an important contribution to other related research. It may also be helpful to state what the proposal does not expect to accomplish or address. The introduction may also specify the order and arrangement of the sections included in the proposal.

**Project Goals and Objectives:** Goals and objectives are not the same and should be dealt with separately. The goal of the project is what will be accomplished as a result of the completed project. Objectives are statements of precise outcomes that can be measured in support of the project's goals. Properly written objectives should be specific, measurable, and time bound. Unless specifically requested by the sponsor, do not include milestone activities, which are more appropriate to periodic technical reports that are usually requested during the life of the sponsored research project.

**Ability of the Project Staff to Undertake This Project:** Sponsors want assurance that the funds invested in a project will yield results. One indicator of success is the researcher's professional reputation and past experiences in managing sponsored research projects. A background discussion of the researcher's own previous work, including evidence of the researcher's competence in the field, previous related work undertaken, and how this new proposal will continue or enhance that previous work should be included as background information. Some sponsors also want to know who has funded the previous work. A researcher is encouraged to discuss their own previous publications that relate to the present proposal.

**Description of Relevant Institutional Resources:** It is useful to think of this section of the proposal as an opportunity for the researcher to assure the proposed sponsor that the institution is solidly in support of the research proposal, has the resources to devote to the project's undertaking, and is willing to commit a portion of those resources to this project. Some administrative areas have boilerplate text already developed that outlines the institution's demonstrated competence in the pertinent research area, unique or unusual research facilities or instruments available to the project staff, and support services and staff available to assist the project.

**Review of the Literature:** Discussions of work done by others should give the reviewer a clear impression of how this project will build upon what has already been done. Additionally, a review of the literature will highlight how the project under consideration differs from other related projects. It is important to establish what is original in the project's approach, what circumstances have changed since related work was done, or what is unique about the time and place of the currently proposed research.

Literature reviews should be selective and critical. Reviewers do not want to read through a voluminous working bibliography; they want to know the especially pertinent works and a fair evaluation of them. A list of works, neither evaluated nor studied, contributes almost nothing to the proposal. The style of the bibliographic item itself depends on the discipline. The main consideration is consistency. Whatever style is chosen, the style should be followed scrupulously throughout the proposal.

**Description of Proposed Research:** A project must always be considered as an allocation of resources toward a specified goal. Using this definition as a framework, the project description is the heart of the proposal and is the primary concern of the technical reviewers. It should persuasively describe what is to be undertaken and how it will be accomplished. The comprehensive explanation of the proposed research is addressed not to the general reader, but to other specialists in the field. Some points to consider when writing this section of the proposal:

- Be realistic in designing the program of work. Overly optimistic notions of what the project can accomplish in one, two, or three years or of its effects on the world will only detract from the proposal's chances of being approved. The proposal should distinguish clearly between long-range research goals and the short-range objectives for which funding is being sought.
- Develop a clear timeline of activities that will be accomplished during each phase of the project. Try to be as detailed as possible about the schedule of the proposed work. When will the first step be completed? When can subsequent steps be started? For complex projects, a calendar detailing the projected sequence and interrelationship of events often gives the sponsor assurance that the investigator is capable of careful step-by-step planning. Project management tools can be used effectively for this purpose.
- Be explicit and concrete in outlining any assumptions or hypotheses on which the research rests.
- Be clear about the focus of the research. In defining the limits of the project, especially in exploratory or experimental work, it is helpful to pose the specific question or questions the project will answer.
- Be specific about the means of evaluating the data or the conclusions. Try to imagine the questions or objections of a hostile critic and show that the research plan anticipates them.
- Be certain that the connection between the research objectives and the research method is evident. The reviewer must see this connection if the proposal is to be given any further consideration. It is better here to risk stating the obvious than to risk the reviewer assuming that the approach and methodology have not been carefully developed and thought out.

**Plan of Action, Methodology, and Design:** Methodology of a project is clearly and directly related to the project description. While the description outlines in more general terms what the project is about and how long it will take to complete, the action plan spells out in specific steps and procedures how the research will take place. This section of the proposal typically answers four important questions in exacting detail:

- The time frame in which the project will take place.
- How long it will take to accomplish the goals of the project.
- Where the project work will be performed.
- How the researcher will accomplish each aspect of the work.

The plan or methods section will be the longest section of the technical narrative and will present a description of the work to be done in accomplishing the project objectives. It should account for all activities and individuals to be involved in the project. This section of the proposal often includes a time chart or flow chart showing the order of activities to take place. Two commonly used project management tools are:

- Program Evaluation and Review Technique (PERT): PERT is a project management technique for determining how much time a project needs before it is completed. Each activity is assigned a best, worst, and most probable completion time estimate. These estimates are used to determine the average

completion time. The average times are used to figure the critical path and the standard deviation of completion times for the entire project.

- **GANTT Chart:** A GANTT chart is a graphic display of activity duration. It is also referred to as a bar chart. Activities are listed with other tabular information on the left side with time intervals over the bars. Activity duration is shown in the form of horizontal bars.

In determining the total length of the project, it is important to remember to incorporate interview and hiring schedules into the total time needed to complete the project. If new staff are to be hired, particularly when they are coming from outside the community, it may well mean an additional four months added to the project's timetable. Sponsors will want to know if any project activities will be happening during the start-up months, what those activities are, who will be doing them, and how those activities will be funded. Explicit detailed scheduling presents a more organized and well thought-out plan than vague statements such as "staff will be hired."

**Project Staffing:** The explanation should specify how many persons at what percentage of time and at what administrative level will be participating in the project. If the program is complex and involves people from other departments or colleges, the organization of the staff and the lines of responsibility should be made clear. Project position descriptions should be included in the appendices.

A plan for staff training is another area frequently overlooked in proposal development. Again, a sponsor will want to be assured that once hired, and when applicable, staff will be trained in a manner that is consistent with national standards for the work to be performed, staff will have the opportunity to thoroughly learn the skills needed to successfully do the work of the project, and the training will support the efficient use of project funds.

If a consultant is to be used to accomplish specific project tasks, the researcher should provide a description of the work to be performed and the length of time the project will need the consultant's services.

**Current and Pending Support:** Many sponsors request that applicants supply information on both active and pending support. Faculty should include a complete list of current sponsored projects including project titles, funding sources, duration of projects, and total approved budgets. This information should be included in the appropriate spaces on required application forms or, in the absence of any required form, typed neatly on a separately numbered page in the appendix to the proposal.

Faculty should also list the same information about pending applications. This information is particularly important when applying to federal programs for which possible sources of support may come from several different funding agencies. Private foundations often want to know if the proposal under consideration has also been submitted to other foundations for support.

**Facilities and Equipment:** Information pertaining to resources available to the principal investigator for the conduction of the project should be described in detail. Examples of such resources include lab space, equipment, animal facilities, library resources, and computer systems.

**Evaluation:** Well-planned research proposals include a method of evaluating the success of the project. Evaluation represents the logical conclusion to the proposal and sends a clear message that the researcher

has not only thought through the execution of the project, but is also concerned that the stated goals have been achieved. Most sponsors ask that an evaluation methodology and outcome statement be part of the submitted proposal. These two parts of the evaluation are known as product and process evaluation. Product evaluation judges the end result of the project.

To write an effective product evaluation section, the researcher must first have had clearly defined and measurable objectives for the project. The process evaluation measures how well the execution of the project matched the plan initially proposed. Did each step outlined in the initial plan support the development of the final product? Were changes to the plan incorporated to accommodate new data or to compensate for some aspect of the initial plan that did not work? While the evaluation stage may seem anticlimactic, a well developed evaluation process can force the researcher to more carefully articulate the project's objectives.

## **Budget**

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The purpose of this section is to introduce cost categories in the proposed budget, discuss the need for budget justification, and introduce a number of Dartmouth College policies and procedures affecting sponsored research budgets. The principal investigator is encouraged to provide a draft of the budget to OSP for review as soon as possible in the proposal preparation process.

The proposal budget should delineate the entire cost of the project, list the amount being requested from the sponsor, and identify project costs that will be met by other sources. The proposal's budget must accurately reflect necessary project costs that are allowable and reasonable. These costs must also be supported by budget documentation. Elements of most budgets include direct costs, indirect costs, cost sharing, and a budget justification. The budget should clearly state to the sponsor how much the entire project will cost and what the specific cost categories are.

If the project is well thought out, the budget will reflect the methodology described within the proposal narrative. Most reviewers will be able to determine if sufficient funds are being requested to successfully complete the project and those costs are reasonable given the scope of work.

Accuracy and detail are essential in this section. Again, researchers are encouraged to follow a sponsor's guidelines exactly. Be sure to show all costs related to the project. Keep in mind that sponsors will support costs that are reasonable and justified in a budget description.

**Direct Costs:** Direct costs are directly linked with carrying out the work of the project.

- **Salaries and wages:** The time and effort of all personnel should be included in the budget. Proposed salaries must be in accordance with institutionally approved salary scales and position grades. For information and advice on salary ranges and position grade levels, contact the Office of Human Resources. In developing a multi-year project budget, remember to factor in salary increases. Allow for flexibility in hiring by requesting sufficient salary funding to attract the best qualified or most experienced applicant.
- **Fringe benefits:** Fringe benefits include such items as health insurance, retirement benefits, and federal withholdings. Rates are contingent on the type of appointment each staff holds. The rate must be charged to the grant in relationship to the salaries and percentage of effort charged to the grant. For multi-year projects, the fringe benefits can be increased by up to one percent per project year. Obtain current fringe benefit rates from the OSP homepage.

- **Consultants:** Consultants provide technical expertise for a limited duration necessary for the conduct of the sponsored project. A consultant is not considered an employee of the institution.
- **Equipment:** Equipment critical to carrying out the project should be listed with a catalog price or accurate estimate of the cost of each item listed. Capital equipment is defined as items costing more than \$2,500.
- **Materials and Supplies:** Expendable equipment (up to \$2,500) and supplies should be listed in this section. Each item or group of items should be listed and carefully justified in terms of need.
- **Travel:** Domestic and foreign travel costs include meals, lodging, airfare, and ground transportation. The type and extent of domestic travel and its relationship to the project should be specified. Travel allowances for air travel normally cover the cost of round-trip coach accommodations. Separate projected transportation costs from food and lodging costs. It is often advisable to build staff interview costs into the total cost of project travel.
- **Subcontracts:** Subcontracts and subgrants are agreements by which some scientific or programmatic aspects of a grant or contract made originally to the institution are contracted out to another organization. A subcontract is appropriate when a portion of the research or grant activity will be performed at another institution or by a commercial vendor. The primary proposal to be submitted to a sponsor must include the subcontractor's statement of work and proposed budget. A letter of intent from the proposed contracting organizations should be included with the primary proposal information.

Other direct costs may include services such as those activities performed to support the project effort. Examples may include project-specific postage, installation of equipment and maintenance on equipment, delivery costs, human subject fees, and project-specific telephone service. Some services listed exclusively as part of the project may also be considered subcontract expenses.

**Indirect Costs:** Indirect costs are costs that are not readily identifiable with individual projects. They allow an institution to recover some of the costs associated with supporting the research project. In developing the indirect cost rate, expenses such as utilities and library use are factored. These costs must be included in all budgets as a percent of total direct costs, excluding services and subcontract costs.

*Please note that indirect costs rates and allowances, as listed below for Dartmouth College, may vary from institution to institution.*

Indirect costs are computed into the final cost of the project using a rate that has been established between Dartmouth College and the federal government. Indirect cost rates are fixed for a negotiated period of time and are consistent for all grant or contract applications unless the sponsor prohibits indirect costs or designates another rate. OSP may negotiate a different indirect cost rate that is lower than Dartmouth College's negotiated rate. Exceptions must be requested in writing and sent to the appropriate dean.

The off-campus indirect cost rate is to be charged only on those projects conducted at sites outside of Hanover and areas immediately surrounding Hanover. The VA in White River Junction has a special research rate of 30 percent; rent should be included as a direct cost item at \$36 per square foot.

In all other projects not conducted in Dartmouth-owned buildings, rent should not be included as a direct cost item if the on-campus rate is used. Rent is automatically included in the on-campus indirect costs and will be paid out of the indirect costs recovered.

Indirect costs cannot be charged on equipment, alterations and renovations, patient care costs, rental and maintenance of off-site facilities, tuition remission, scholarships and fellowships, and subcontract amounts over \$25,000.

**Budget Justification:** The budget justification is the researcher's opportunity to describe in some detail any budget expenses that need further clarification or explanation.

## Cost Sharing and Matching Funds

Some sponsors require that the college contribute a certain portion of funding to the overall cost of a project or the purchase of a piece of equipment. This contribution may come from in-kind (non-cash) or cash contributions and must be approved by the appropriate official. For this reason, be sure to obtain written authorization for cost sharing before writing or submitting a proposal requiring this kind of commitment by the college.

**Definitions:** Cost sharing is that portion of the total costs—direct and indirect—of a sponsored project or program that meets the following criteria:

1. It is not provided by the sponsor.
2. It is included in the itemized costs of the project or program's budget that has been approved by the sponsor.

Cost sharing as defined above may be included in either of the following categories:

- Mandatory cost sharing—cost contribution required of the grantee by the sponsor as a condition of the award, such as the matching requirements of challenge grants.
- Voluntary cost sharing—cost contribution voluntarily offered by the principal investigator and accepted by the sponsor in the program budget.

**Federal Regulations Regarding Cost Share Dollars:** To be acceptable for cost sharing:

- Per OMB Circular A-21, costs must:
  - Be allocable, i.e., necessary and reasonable for proper and efficient accomplishment of project or program objectives.
  - Be allowable under the applicable cost principles.
- Per OMB Circular A-110, costs must:
  - Be verifiable from the grantee's records.
  - Not be included as contributions for any other federally-assisted project or program.

- o Not be paid by the federal government under another award, except when authorized by federal statute to be used for cost sharing or matching.
- o Be provided for in the approved budget when required by the federal awarding agency.
- o Not be unrecovered indirect costs without prior approval of the federal awarding agency.
- o Conform to all other applicable provisions of OMB Circular A-110.

**Required Approvals for Cost Sharing:** When cost sharing appears on a proposal budget, the source, type, and amount of funds should be identified and authorized by the signature of the appropriate dean. If the proposal budget contains required matching funds, the development office should also review it to ascertain who is responsible for raising the funds externally.

**Recording of Cost Share Transactions:** OSP records the direct portion of a cost share transaction initially by charging (under the appropriate subcode) a sponsored account specifically created to capture the cost share related to a given sponsored project or program and subsequently by transferring the charge from the sponsored account to the principal investigator's departmental account through the use of certain subcodes [*please note these code numbers will vary from institution to institution*] (1990 for transactions related to salary and fringe, and 5910 for transactions related to non-salary dollars).

The indirect portion of a cost share transaction is recorded initially by charging the sponsored account under subcode 7810 and crediting the appropriate revenue or pool account under subcode 7910 and subsequently by reversing this entry, such as crediting the sponsored account under subcode 7900 and debiting the revenue or pool account under subcode 7900.

Significant (greater than five percent) variations from the proposal budget in the effort which a principal investigator expends on a particular sponsored project or program during the course of the project or program are recorded and certified by the principal investigator in Section 7 of the Payroll Authorization form. These variations represent additional salary-related cost share above and beyond that included in the proposal budget.

## Appendices

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Appendices in the proposal should be clearly labeled and provide supportive information that relates directly to the proposed project. In general, appendices will include any supportive data, curriculum vitae for key personnel, and relevant certifications. Consult the sponsor's proposal guidelines when putting together the proposal appendices. Many sponsors have limits on the number of appendices that may be attached or the overall number of pages the total proposal may include. Total page count may or may not include appendices.

**Curriculum Vitae, Biosketch, or Resume:** Current curriculum vitae are included for all key project personnel. Follow the sponsor guidelines on format and length of documents.

**Letters of Support:** Letters of support for the project are frequently requested by a sponsor. Select colleagues who will be able to write a strong and persuasive letter about the project's expected benefits to

the research community and the applicant's ability to carry out the project. Three to five letters are usually considered sufficient. Again, follow the sponsor's guidelines regarding letters of support. Remember to request letters of support far enough in advance; usually, one month is sufficient lead time. Letters of support should be sent directly to the principal investigator or the appropriate administrative assistant.

**Certifications:** By signing a certification, the college through the institutional official has assured the sponsor that certain levels of behavior or ways of conducting research are guaranteed. Certifications listed may imply the college or the principal investigator as the grantee, depending on the type of certification. The following presents an overview of the information contained in the most commonly required certifications. Complying with required certifications may involve a complex and lengthy review process. Principal investigators are encouraged to contact the OSP staff regarding compliance with specific certifications.

- **Conflict of Interest:** The purpose of this disclosure statement is to give the college the information needed to identify potential conflicts of interest for investigators and other key personnel involved in sponsored activities, and to ensure that no unresolved conflict exists between their sponsored activities and their outside interests and activities. This statement conforms with current federal and college guidelines requiring disclosure of professional activities and financial holdings of investigators and other key personnel.

Under Dartmouth College's conflict of interest policy, all investigators and other key personnel involved in a sponsored project must complete this form on an annual basis and any time new circumstances would create a potential or actual conflict of interest. The form should be submitted to the director of sponsored projects. Each time a proposal is submitted by the principal investigator, he or she must sign the routing form indicating compliance with Dartmouth College's conflict of interest policy.

- **Drug-Free Workplace:** By signing this certification, the institution agrees to a certain set of actions related to the handling of situations involving illegal drugs in the workplace.
- **Lobbying:** By signing this certification, the institution agrees to refrain from attempting to influence any federal, state, or local election; referendum; initiative; or similar procedure through in-kind or cash contributions, endorsements, publicity, or similar activity.
- **Intellectual Property Rights:** Intellectual property protection may include copyrights, patents, protection of trade secrets, and trademarks. The Dartmouth College Copyright Policy governs copyright ownership of works created by Dartmouth faculty and other classes of employees. A trade secret is any invention or other valuable business information that is not protected by a patent and is not known or accessible to others. To be protected as a trade secret, the information or invention must be used in a business, and positive measures must be employed to keep it secret. Since a university's task is exactly the opposite—the dissemination of technical information—universities are seldom involved with trade secrets. Trademarks are defined as “any word, name, symbol, or device or any combination therefore adopted and used by a manufacturer or merchant to identify his goods and distinguish them from those manufactured or sold by others.” The Technology Transfer Office staff can assist researchers with questions related to intellectual property rights.
- **Misconduct in Science Policy:** Misconduct means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data. The National Science Foundation additionally includes a “material failure to comply with Federal requirements for protection of researchers, human subjects or the public or for ensuring the welfare of laboratory animals; or a failure to meet other material legal requirements governing research” in the definition of misconduct.

- **Use of Human Subjects:** All research involving human participation must be reviewed by the Committee for the Protection of Human Subjects (CPHS) under the administrative direction of the institutional review board (IRB) Administrator. The primary role of CPHS is to protect the rights and welfare of research participants. The CPHS office is a source of information for students, faculty, and study coordinators. Although it is ultimately the responsibility of the principal investigator to follow appropriate procedural requirements, it is an objective of the Assistant Director of CPHS to assist the investigator in that process. While use of human subjects is usually thought of as medically related research, it must be stressed that research proposals involving human subject participation should be referred to CPHS.
- **Use of Animal Subjects:** All research involving the use of animals must be reviewed by the Institutional Animal Care and Use Committee (IACUC). An Animal Subjects Review form should be obtained from the Animal Resource Center and completed for consideration at a meeting of IACUC.
- **Use of Radioisotopes:** All research involving the use of radioisotopes must be reviewed by the Radiation Safety Office. Principal investigators should contact the Radiation Safety Office before submitting a proposal if they intend to use radioactive materials in their sponsored research project.
- **Recombinant DNA and Carcinogens:** All research involving the use of recombinant DNA or carcinogens must be reviewed by the Environmental Health and Safety Office. Principal investigators should contact the Biosafety Committee of the Environmental Health and Safety Office for recombinant DNA or Environmental Health and Safety Office before submitting a proposal that includes the use of these materials.

**Grant History:** Many sponsors request applicants to supply information on both active and pending external support. This information will either be requested on a form supplied by the sponsor or should be included as an appendix in the proposal. An administrative area or an individual faculty member will be asked to include a complete list of current sponsored and pending projects, including project titles, funding sources, duration of projects, and total approved budgets.

**Position Descriptions:** Position descriptions should be included as part of the appendices for all project staff. The Department of Human Resources can provide sample position descriptions and assist the researcher in classifying the position. The tasks, responsibilities, and qualifications outlined in the position description should accurately reflect responsibilities as described in the text of the proposal.

**Suggested Reviewers:** Principal investigators may suggest appropriate reviewers for government sponsored proposals. As with letters of support, the principal investigator should suggest colleagues who will understand the nature of the research proposed, be able to accurately evaluate the methodology to be employed, and the appropriateness of the level of funding sought. With a sufficient explanation, principal investigators may also designate persons they would prefer not review the proposal. All suggestions should be submitted in a cover letter or separate sheet included in the proposal package.

## Reference

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1. Boston College, Office of Sponsored Research. *Sponsored Research Manual*. Online. <http://www.bc.edu/research/osp/policies/>. Accessed July 3, 2006.

# Clinical and Industry Research

## What Are Clinical Trials?

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Before a pharmaceutical or biotechnology company can initiate testing in humans, it must conduct extensive preclinical or laboratory research. This research typically involves years of experiments in animal and human cells. The compounds are also extensively tested in animals. If this stage of testing is successful, a company provides this data to the Food and Drug Administration (FDA) by submitting an Investigational New Drug application (IND). The application requests approval to begin testing the drug in a clinical trial.

A clinical trial is a research study in human volunteers to further explore the preclinical or laboratory research. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people and ways to improve health. Interventional trials determine whether experimental treatments or new ways of using known therapies are safe and effective under controlled environments. Observational trials address health issues in large groups of people or populations in natural settings.

## What Are the Different Types of Clinical Trials?

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**Treatment trials** test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

**Prevention trials** seek better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.

**Diagnostic trials** are conducted to improve tests or procedures for diagnosing a particular disease or condition.

**Screening trials** test the best way to detect certain diseases or health conditions.

**Quality of life trials** (or supportive care trials) explore ways to improve the comfort and quality of life for individuals with a chronic illness.

The clinical testing of experimental drugs is normally done in three phases, with each successive phase involving a larger number of people. Once FDA has granted a New Drug Approval (NDA), pharmaceutical companies also conduct post-marketing or late phase III/phase IV studies.

### Phase I Study

Phase I studies are primarily concerned with assessing the drug's safety. This initial phase of testing in humans is done in a small number of healthy volunteers (20 to 100), who are usually paid for participating